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भारतीय मानक

चिकित्सीय विद्युत उपस्कर

भाग 2 सुरक्षा के लिए विशिष्ट अपेक्षाएँ

अनुभाग 17 अपने आप-नियंत्रित ब्राचीचिकित्सीय आफटरलोडिंग उपस्कर

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 2 PARTICULAR REQUIREMENTS FOR THE SAFETY

Section 17 Automatically-Controlled Brachytherapy Afterloading Equipment

ICS 11.040.60: 19.100

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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Price Group 11

Electromedical Equipment Sectional Committee, MHR 15

NATIONAL FOREWORD

This Indian Standard (Part 2/Sec 17) which is identical with IEC 60601-2-17 : 2005 'Medical electrical equipment — Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on the recommendation of the Electromedical Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of IEC Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

Only the English text of the International Standard has been retained while adopting it as an Indian Standard, and as such the page numbers given here are not same as in the IEC Publication.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
IEC 60601-1 : 1988[1] Medical electrical equipment — Part 1: General requirements for safety	IS 13450 (Part 1) : 1994 Medical electrical equipment: Part 1 General requirements for safety	Identical
IEC/TR 60788 : 2004 Medical electrical equipment — Glossary	IS 13807 : 1994 Medical radiology — Terminology	Technically Equivalent
IEC 60601-2-7 : 1998 Medical electrical equipment — Part 2-7: Particular requirements for the safety of high voltage generators of diagnostic X-ray generators	IS 13450 (Part 2/Sec 7) : 2006 Medical electrical equipment: Part 2 Particular requirements for the safety, Section 7 High-voltage generators of diagnostic X-ray generators	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
IEC 61217 : 1996	Radiotherapy equipment — Coordinates, movements and scales
IEC 62083 : 2000	Medical electrical equipment — Requirements for the safety of radiotherapy treatment planning systems

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[1] Since revised in 2005.

(*Continued on third cover*)

IS 13450 (Part 2/Sec 17) : 2007
IEC 60601-2-17 : 2005

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 2 PARTICULAR REQUIREMENTS FOR THE SAFETY

Section 17 Automatically-Controlled Brachytherapy Afterloading Equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

1.1.101 This Particular Standard specifies requirements for the safety of automatically-controlled EQUIPMENT for BRACHYTHERAPY of patients using AFTERLOADING techniques.

1.1.102 This Standard specifies requirements for automatically-controlled AFTERLOADING EQUIPMENT

- which contains and uses only beta, gamma, and NEUTRON-emitting SEALED RADIOACTIVE SOURCES,
- which automatically drives the sealed radioactive source(s) from a storage container to a treatment position inside the source applicator(s) and returns the source(s) to the storage container,
- which is designed for connection to a PATIENT, and
- with which movements of the RADIOACTIVE SOURCE(S) are carried out automatically by the EQUIPMENT according to a prescribed programme using a powered mechanism whose changes are controlled by the CONTROLLING TIMER(S) and TIMING DEVICES that are either PROGRAMMABLE ELECTRONIC SUB-SYSTEMS (PESS) (computer or microprocessors) or non-programmable systems.

1.1.103 This Standard specifies requirements for EQUIPMENT intended to be

- used under the supervision of QUALIFIED PERSONS;
- maintained at predetermined intervals;
- subject to regular checks by the user.

This Standard does not specify requirements for SEALED RADIOACTIVE SOURCES used with the EQUIPMENT. Such requirements are specified in other standards (see 6.8.3).

1.1.104 The requirements of this Standard are based on the assumptions that:

- a TREATMENT PLAN is available that prescribes appropriate values of the TREATMENT PARAMETERS, and
- the SOURCE STRENGTH(S) of the RADIOACTIVE SOURCE(S) used by the EQUIPMENT is (are) known.

This Standard includes requirements intended to ensure that the prescribed values of the TREATMENT PARAMETERS can be achieved by the EQUIPMENT, in particular that:

- the selected RADIOACTIVE SOURCE(S) is (are) positioned or moved within the SOURCE APPLICATOR in the selected configuration relative to the SOURCE APPLICATOR;
- IRRADIATION is performed by the selected RADIOACTIVE SOURCE configuration for the selected duration;
- IRRADIATION is performed by the EQUIPMENT without causing unnecessary risk to the OPERATOR or other persons in the immediate surroundings.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for safety of automatically-controlled BRACHYTHERAPY AFTERLOADING EQUIPMENT and the compliance test specifications. It presents the general functional requirements of the demand for safety rather than particular technological means of implementation.

1.3 Particular Standards

ADDITION:

1.3.101 Relationship to the General Standard

This Particular Standard is to be read in conjunction with IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, with its Amendments 1 (1991) and 2 (1995) – hereinafter referred to as the General Standard – which it amends and supplements. As in the General Standard, the requirements are followed by compliance tests.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General and Collateral Standards are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard;

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard;

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses, figures or tables which are additional to those of the General Standard are numbered starting from 101: additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

The term "this Standard " is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard.

1.3.102 Relationship to other standards and documents

NOTE See Appendix L for normative references.

1.5 Collateral Standards

Addition:

1.5.101 IEC 60601-1-1

All clauses and subclauses of Collateral Standard IEC 60601-1-1apply.

1.5.102 IEC 60601-1-2

All clauses and subclauses of Collateral Standard IEC 60601-1-2 apply.

1.5.103 IEC 60601-1-3

Collateral Standard IEC 60601-1-3 does not apply.

1.5.104 IEC 60601-1-4

All clauses and subclauses of Collateral Standard IEC 60601-1-4 apply.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition:

For the purposes of this document, the terms and definitions given in the General Standard or in its Collateral Standards and the following apply.

NOTE 1 The Index of defined terms at the end of this document lists defined terms alphabetically with their source reference.

NOTE 2 In this Particular Standard, IRRADIATION refers to the entire process of exposing the patient to RADIOACTIVE SOURCES in positions and for periods of time appropriate for TREATMENT. TRANSIT times are explicitly excluded from the TREATMENT TIME.

NOTE 3 Although the actual titles of the persons fulfilling the following roles may vary from country to country, in this Particular Standard the term 'OPERATOR' is used to denote the person controlling the BRACHYTHERAPY EQUIPMENT during treatment, and the term 'USER' to denote the organization or individual responsible for the use and maintenance of the BRACHYTHERAPY AFTERLOADING EQUIPMENT. The terms 'radiotherapist' and 'radiation oncologist', although not used in this Particular Standard, are used in many countries to denote the person exercising medical supervision and responsibility for determining and prescribing PATIENT treatment.

2.1 EQUIPMENT parts, auxiliaries and ACCESSORIES

Additional definitions:

2.1.101
ABBREVIATIONS
The following abbreviations are used in this standard:

– PESS	programmable electronic sub-system
– SFC	single fault condition
– TCP	treatment control panel

2.1.102
BETA SOURCE STRENGTH
ABSORBED DOSE RATE [Gy s^{-1}] in water at 2 mm along the perpendicular bisector from a RADIOACTIVE SOURCE emitting beta RADIATION

2.1.103
BRACHYTHERAPY
INTRACAVITARY, INTERSTITIAL, SUPERFICIAL or INTRALUMINAL RADIOTHERAPY using one or more SEALED RADIOACTIVE SOURCES

2.1.104
CONTINUATION
in <RADIOTHERAPY>, re-starting IRRADIATION after INTERRUPTION of IRRADIATION without re-selection of OPERATING conditions

2.1.105
DWELL TIME
time a RADIOACTIVE SOURCE or a RADIOACTIVE SOURCE TRAIN remains at a selected TREATMENT position

2.1.106
GAMMA SOURCE STRENGTH
REFERENCE AIR KERMA RATE of a BRACHYTHERAPY SOURCE emitting gamma rays. The unit of GAMMA SOURCE STRENGTH is Gy s^{-1} at 1 m

NOTE Multiples (milli, mega, etc.) are permitted.

2.1.107
INITIATION
in <RADIOTHERAPY>, commencing IRRADIATION from the READY STATE when the READY STATE was attained by carrying out selection and confirming the operating conditions and not by INTERRUPTION OF IRRADIATION

2.1.108
INTERRUPTION OF IRRADIATION, TO INTERRUPT RADIATION
stopping IRRADIATION prior to TERMINATION OF IRRADIATION with the possibility of CONTINUATION without reselection of operating conditions

2.1.109
INTRALUMINAL RADIOTHERAPY
RADIOTHERAPY in which one or more RADIOACTIVE SOURCES, with or without SOURCE APPLICATORS, are introduced into a body lumen such as a blood vessel, airway, or the gastrointestinal tract

2.1.110
NEUTRON SOURCE STRENGTH
dose rate of a brachytherapy source emitting neutrons. The unit of NEUTRON SOURCE STRENGTH is Gy s^{-1} at 1 m

2.1.111
QUALIFIED PERSON
person recognized by a competent authority as having the requisite knowledge and training to perform particular duties

2.1.112
RADIOACTIVE SOURCE TRAIN
sequence of SEALED RADIOACTIVE SOURCES, possibly separated by non-RADIOACTIVE spacers, either permanently combined or selected prior to each IRRADIATION, and used in AFTERLOADING EQUIPMENT. The RADIOACTIVE SOURCE TRAIN is usually selected to give a specified dose distribution

2.1.113
REFERENCE AIR KERMA RATE
air kerma rate, at a reference distance of 1 m, after correction for air attenuation and scattering

NOTE The reference air kerma rate, K_R, is similar to the air kerma strength, S_K, used in the USA, which is the product of air-kerma rate in free space and the square of the distance of the calibration point from the source centre along the perpendicular bisector.

2.1.114
SOURCE STRENGTH
GAMMA SOURCE STRENGTH, BETA SOURCE STRENGTH, or NEUTRON SOURCE STRENGTH of a RADIOACTIVE SOURCE, whichever is applicable for the intended use of the EQUIPMENT

2.1.115
TERMINATION OF IRRADIATION
stopping or preventing further IRRADIATION with no possibility of re-starting without the reselection of operating conditions (i.e., returning to the PREPARATORY STATE)

2.1.116
TRANSIT
the period during which the RADIOACTIVE SOURCES move from the STORAGE CONTAINER(S) to a treatment position or move from a treatment position to the STORAGE CONTAINER(S)

2.1.117
TREATMENT PARAMETER
factor that describes one aspect of the irradiation of a patient during radiotherapy, such as radiation energy, absorbed dose, treatment time

2.1.118
TREATMENT TIME
the sum of the DWELL TIMES which constitute a TREATMENT

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.1 Tests

Addition:

Appropriate care should be taken to carry out compliance tests safely, for example by using a non-RADIOACTIVE SOURCE wherever possible. TYPE TESTS described in this Particular Standard may also be used by the MANUFACTURER or by the installer as routine tests.

5 Classification

Replacement:

EQUIPMENT and its APPLIED PARTS shall be classified and marked/identified as described in Clause 6. This includes:

5.1 According to the type of protection against electric shock:

- EQUIPMENT within the scope of this standard shall be CLASS 1 EQUIPMENT.

5.2 According to the degree of protection against electric shock:

- APPLIED PART within the scope of this Standard shall be TYPE B APPLIED PART, unless otherwise specified.

5.3 According to the degree of protection against ingress of water detailed in IEC 60529 – IPX0, unless otherwise specified.

5.4 According to the method(s) of sterilization or disinfection recommended in the INSTRUCTIONS FOR USE.

5.5 According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE:

- EQUIPMENT within the scope of this Standard shall be EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE or as otherwise specified.

5.6 According to the mode of operation:

- EQUIPMENT within the scope of this Standard shall be suitable for CONTINUOUS OPERATION.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

z) Removable protective means

Replacement:

EQUIPMENT shall be declared as unsuitable for alternative applications that require the removal of a protective means to utilise a particular function.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

Additional items:

aa) The EQUIPMENT shall be provided with permanently affixed and clearly legible markings on the appropriate part showing:

   1) the maximum total SOURCE STRENGTHS of each of the RADIONUCLIDES for which the EQUIPMENT is designed;
   2) the symbol ISO 361 indicating possible radiation hazard;
   3) the requirement for the STORAGE CONTAINER(s) to be located only in a treatment room with restricted access, if this is specified (see 30.1.1);
   4) additional external supply requirements (e.g. compressed air), if any.

bb) For EQUIPMENT with more than one RADIOACTIVE SOURCE, the EQUIPMENT shall be provided with a permanently affixed means (e.g. a PESS) by which either the USER or the MANUFACTURER can indicate the RADIOACTIVE SOURCES and their configurations that can be selected for each CHANNEL.

cc) The EQUIPMENT shall be provided with a permanently affixed means by which either the USER or the MANUFACTURER can indicate the RADIONUCLIDE(S) that are being kept in the STORAGE CONTAINER(S) and its/their SOURCE STRENGTH(S) on given date(s).

dd) Each interchangeable SOURCE APPLICATOR shall be permanently marked, or where appropriate, marked on the packaging, with specific identification.

ee) Each rigid SOURCE APPLICATOR with a clinically significant asymmetrical feature (e.g. curved or partially shielded) and capable of insertion into a PATIENT in different orientations shall be so marked that its orientation can be identified after insertion unless the ACCOMPANYING DOCUMENTS contain a recommendation that radiographic or other appropriate checks be carried out.

NOTE The identification of BRACHYTHERAPY SOURCE activity (e.g. in curies or becquerels) is required by some regulatory agencies.

6.7 Indicator lights and push-buttons

A) COLOURS OF INDICATOR LIGHTS

Replacement:

Where indicator lights are used on the TREATMENT CONTROL PANEL, or on other control panels, the colours of the lights shall accord with the following:

– Immediate action required in response to an unintended state of operation	Red
– RADIOACTIVE SOURCE(S) at the treatment position(s)	Yellow
– RADIOACTIVE SOURCE(S) in TRANSIT	Yellow (flashing)
– READY STATE	Green
– EQUIPMENT switched on but all the operations required to reach the READY STATE not yet carried out	White

The status of the EQUIPMENT shall be indicated also by means other than the colour; e.g., by the shape or location of the indicator, or by accompanying text.

For AFTERLOADERS other than those intended to be operated in the vicinity of the patient, indicator lights in the TREATMENT ROOM but not on the TREATMENT CONTROL PANEL to indicate that the RADIOACTIVE SOURCE(S) is (are) either at the treatment position(s) or in TRANSIT should be coloured red. This colour is required because any USER in the TREATMENT ROOM observing a red light should take immediate action.

6.8 ACCOMPANYING DOCUMENTS

6.8.2 INSTRUCTIONS FOR USE

d) Cleaning, disinfection and sterilisation of parts in contact with the PATIENT

Addition:

INSTRUCTIONS FOR USE shall also include a warning of the risk that may arise during wet or steam sterilisation whereby liquids may become trapped in cavities and subsequently transferred to other parts of the system. This warning shall include the risk of corrosive damage to the SEALED RADIOACTIVE SOURCE(S) and the SOURCE DRIVE MECHANISM(S) in the event that trapped liquids are present.

e) MAINS operated EQUIPMENT with additional power source

Replacement:

INSTRUCTIONS FOR USE shall include instructions for carrying out and recommendations on the frequency of all periodic checking, maintenance and recharging of batteries and of any other additional internal power source(s).

Additional items:

aa) Checking INTERLOCKS

INSTRUCTIONS FOR USE shall contain instructions for carrying out and recommendations on the frequency of checks on all INTERLOCKS.

bb) Checking the security of couplings and connections

INSTRUCTIONS FOR USE shall contain instructions for the procedures to be carried out to check the security of the connection, if any, of RADIOACTIVE SOURCE(S) to SOURCE DRIVE MECHANISM(S), and of the couplings of CHANNEL(S) to SOURCE APPLICATOR(S).

cc) Need for special procedures after a failure of a CONTROLLING TIMER

INSTRUCTIONS FOR USE shall contain an explanation of the need for special procedures after a failure of a CONTROLLING TIMER (see 30.3.2 c) of this Particular Standard).

dd) Failure of RADIOACTIVE SOURCE to return to the STORAGE CONTAINER

INSTRUCTIONS FOR USE shall contain advice on the recommended procedures to be adopted in the case of failure of a RADIOACTIVE SOURCE to return to the STORAGE CONTAINER and on any emergency EQUIPMENT that may be required.

ee) TRANSIT ABSORBED DOSE

INSTRUCTIONS FOR USE shall contain information on AIR KERMA (or ABSORBED DOSE) at the positions specified in 50.1.4 of this Particular Standard by the TRANSIT from the STORAGE CONTAINER to the TREATMENT position and the return of a specified RADIOACTIVE SOURCE.

INSTRUCTIONS FOR USE shall advise that the expected total TRANSIT dose should be determined and, if necessary, allowed for in dose calculations.

INSTRUCTIONS FOR USE shall also contain a warning that the accurate achievement of the prescribed dose may be compromised if many TRANSITS of the RADIOACTIVE SOURCE(S) from and return to the STORAGE CONTAINER are carried out during the treatment.

ff) Limitations of CHANNELS and SOURCE APPLICATOR(S)

INSTRUCTIONS FOR USE shall state:

- the minimum radii of curvature for a specified inside diameter of CHANNEL(S) and SOURCE APPLICATORS which are allowable for normal operation;
- the conditions of the positional arrangements of CHANNEL(S) and SOURCE APPLICATOR(S) under which the agreement required by 50.2.1 of this Particular Standard does not hold, with an explanation of the relation to the clinical purposes for which the EQUIPMENT is specified (see 1.1.104 of this Particular Standard);
- the nature of any obstacles of CHANNEL(S) and SOURCE APPLICATOR(S) that might impede the free passage of RADIOACTIVE SOURCE(S) or RADIOACTIVE SOURCE TRAIN(S).

gg) Check for contamination

INSTRUCTIONS FOR USE shall contain recommendations regarding appropriate checks for leakage of RADIOACTIVITY from the RADIOACTIVE SOURCE(S).

hh) Asymmetric SOURCE APPLICATOR check

Where appropriate (see 6.1) INSTRUCTIONS FOR USE shall contain a recommendation that radiographic or other checks be carried out on the orientation of asymmetric SOURCE APPLICATOR(S).

ii) Functional checks and maintenance

INSTRUCTIONS FOR USE shall contain recommendations to the USER on the regular functional checks to be performed and the required maintenance of the EQUIPMENT that should ensure continued safe use, particularly on the maintenance of the SOURCE DRIVE MECHANISM.

INSTRUCTIONS FOR USE shall, where appropriate, include recommendations to carry out tests using non-RADIOACTIVE SOURCES.

jj) Limitations on source transitions

The INSTRUCTIONS FOR USE shall contain the maximum number of transitions of the RADIOACTIVE SOURCE(S) from the STORAGE CONTAINER to the SOURCE APPLICATOR and back to the STORAGE CONTAINER. If no limit on number of transitions is imposed, the INSTRUCTIONS FOR USE shall state this.

kk) Checking the source strength(s) of the radioactive source(s)

INSTRUCTIONS FOR USE shall contain a recommendation that a measurement be made from which the SOURCE STRENGTH of each newly received RADIOACTIVE SOURCE can be determined with sufficient accuracy and compared with any values used internally by the EQUIPMENT.

6.8.3 Technical description

a) General

Addition:

The technical description shall state:

1) whether the EQUIPMENT is specified and intended for use only with the STORAGE CONTAINER(S) in a TREATMENT ROOM with restricted access (see 30.1.1);
2) the RADIONUCLIDE(S), the corresponding maximum SOURCE STRENGTH(S) of the RADIOACTIVE SOURCE(S) for which the EQUIPMENT is designed and the corresponding LEAKAGE RADIATION from the STORAGE CONTAINER;
3) the range of permissible configurations for the RADIOACTIVE SOURCE TRAIN(S), if any;
4) whether it is permissible to have RADIOACTIVE SOURCES from other suppliers, in which case dimensions and tolerances of the CAPSULES for THE RADIOACTIVE SOURCES shall be stated;
5) the international standards whose requirements the RADIOACTIVE SOURCES should meet, together with any other specific requirements;
6) whether it is permissible to have SOURCE APPLICATORS from other suppliers, in which case relevant dimensions and tolerances shall be stated, and a recommendation given that such SOURCE APPLICATORS should be tested for compliance with requirements on position and security of couplings;
7) the tolerances for:
   - RADIOACTIVE SOURCE positioning during treatment ;
   - transit time;
   - dwell time.

The technical description shall further state:

8) that the requirements in this Particular Standard cannot guarantee that the presence of a RADIOACTIVE SOURCE outside the STORAGE CONTAINER will be indicated under all fault conditions;
9) that the use of an independent radiation monitor appropriate for the radiation type in the vicinity of the PATIENT is recommended;
10) that if provided, an independent radiation monitor adjacent to any part of the EQUIPMENT should be capable of giving a visible indication of RADIATION and should function properly at the maximum radiation levels that might be expected in the vicinity of the EQUIPMENT;
11) that the radiation monitor should continue to function and give the indication for several hours after a power failure (e.g. battery back-up).

The technical description shall contain details for the connection of the suitable device(s) that can ensure an INTERRUPTION (see 30.1.8).

The technical description shall provide guidance and precautions regarding the identification, handling and disposal of equipment or equipment parts that may exhibit RADIOACTIVITY.

The technical description shall include one or more dose distributions that are representative of the clinical use of the device. The dose distribution(s) shall include the influence of the SOURCE APPLICATOR.

SECTION TWO – ENVIRONMENTAL CONDITIONS

10 Environmental conditions

This clause of the General Standard applies except as follows:

10.2.1 Environment

Replacement:

a) Ambient temperature between +15°C and +35 °C.
b) Relative humidity between 30 % and 75 %.
c) Atmospheric pressure between 70 kPa and 110 kPa.
d) Unless otherwise specified by the MANUFACTURER.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply.

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS.

The clauses and subclauses of this section of the General Standard apply.

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the General Standard apply except as follows.

29 X-radiation

Not used.

30 Alpha, beta, gamma, NEUTRON RADIATION and other particle radiation

This clause of the General Standard applies except as follows:

Replacement:

The main requirements of this clause are grouped. The first group of subclauses applies to NORMAL USE and NORMAL CONDITION and its objective is the safe and satisfactory achievement of the prescribed TREATMENT PARAMETERS. The second group is designed to give protection against other than NORMAL USE. The last group of subclauses applies to SINGLE FAULT CONDITIONS and its objective is to protect the PATIENT and the OPERATORS from hazard.

30.1 Protection in NORMAL USE and NORMAL CONDITION

The requirements of this subclause cover the shielded storage of the RADIOACTIVE SOURCES, the indications of their positions, the timing and selection of modes of treatment, and the control of movements. They do not cover the temporary storage of sources under emergency conditions or the transport of the EQUIPMENT from one area with restricted access to another.

30.1.1 Limitation of LEAKAGE RADIATION from the STORAGE CONTAINER(S)

These requirements a) and b) shall be met for each specified STORAGE CONTAINER with all combinations of RADIOACTIVE SOURCES specified in the ACCOMPANYING DOCUMENTS as suitable to be contained within the STORAGE CONTAINER.

a) General use of the STORAGE CONTAINER(S)

This requirement shall be met except where the STORAGE CONTAINER(S) are specified in the ACCOMPANYING DOCUMENTS as being suitable for installation and use only in a TREATMENT ROOM with restricted access.

The DOSE EQUIVALENT RATE at any position 50 mm from the surface of the STORAGE CONTAINER or any other surface permanently fixed to it shall not exceed 0,01 mSv h^{-1}.

The DOSE EQUIVALENT RATE at any position 1 m from the surface of the STORAGE CONTAINER or any other surface permanently fixed to it shall not exceed 0,001 mSv h^{-1}.

Compliance is checked by the following tests:

- *for measurements at 50 mm the DOSE EQUIVALENT RATE shall be averaged over an area up to but not exceeding 10* cm^2*;*
- *for measurements at 1 m the DOSE EQUIVALENT RATE shall be averaged over an area up to but not exceeding 100* cm^2*;*

- *measurements shall be made with the combination of RADIOACTIVE SOURCES that is possible within the specifications given by the MANUFACTURERS and is the least favourable with regard to this requirement.*

b) STORAGE CONTAINER(S) specified for use in a TREATMENT ROOM with restricted access

This requirement shall be met where the STORAGE CONTAINER(S) are stated in the ACCOMPANYING DOCUMENTS as being suitable for installation and use only in the TREATMENT ROOM with restricted access.

The DOSE EQUIVALENT RATE at any position 50 mm from the surface of the STORAGE CONTAINER or any other surface permanently fixed to it shall not exceed 0,1 mSv h^{-1}.

The DOSE EQUIVALENT RATE at any position 1 m from the surface of the STORAGE CONTAINER or any other surface permanently fixed to it shall not exceed 0,01 mSv h^{-1}.

Compliance is checked as specified in 30.1.1 a).

30.1.2 Indication of the position of RADIOACTIVE SOURCES

This subclause specifies the indications that are required to give a warning at the STORAGE CONTAINER and at remote location(s) when the RADIOACTIVE SOURCES are not in the STORAGE CONTAINER, and also to indicate to the OPERATOR that the RADIOACTIVE SOURCES are following the prescribed programme.

a) Indication at the STORAGE CONTAINER(S)

Indicating lights coloured to comply with 6.7 of this Particular Standard or other means of visible indication shall be provided at the STORAGE CONTAINER, arranged to give an indication whenever any RADIOACTIVE SOURCE is transferred from the STORAGE CONTAINER, and to continue that indication until all the RADIOACTIVE SOURCES have returned to the STORAGE CONTAINER.

Compliance is checked by inspection and operation of the EQUIPMENT.

b) Distant warning indication

Where appropriate, EQUIPMENT shall be provided with connections for devices with indicating lights remote from the location described in 30.1.7d) arranged to give indications of the conditions referred to in 30.1.2a) and coloured to comply with 6.7 of this Particular Standard.

Compliance is checked by inspection and operation of the EQUIPMENT.

c) Indication for the operator at the TREATMENT CONTROL PANEL

Indicator lights coloured and arranged to comply with 6.7 of this Particular Standard or other means of indication shall be provided on the TREATMENT CONTROL PANEL and also where the operations referred to in 30.1.7d) are made, if this is different from the TREATMENT CONTROL PANEL:

- to indicate when the RADIOACTIVE SOURCES are in their selected treatment position(s) or carrying out their selected treatment movements within the tolerances specified in 50.2.1;
- to indicate when all RADIOACTIVE SOURCES are correctly positioned in the STORAGE CONTAINER;
- to indicate when RADIOACTIVE SOURCE(S) are in TRANSIT

Compliance is checked by inspection and operation of the EQUIPMENT.

30.1.3 Key control of possibility of pre-setting CONTROLLING TIMER and of selection, confirmation and movement of RADIOACTIVE SOURCES

EQUIPMENT shall be provided with means whereby pre-setting the CONTROLLING TIMER (see 30.1.4), selection and confirmation (see 30.1.6), and movement of RADIOACTIVE SOURCES from the STORAGE CONTAINER (see 30.1.7) are possible only after an operation or activation has been carried out by use of a removable special TOOL (which may be a key) and while the special TOOL or key remains in its operating position.

In addition, pre-setting the CONTROLLING TIMER (see 30.1.4), selection and confirmation (see 30.1.6) shall be possible only after an operation has been carried out by use of an additional key. This key may be a designated PASSWORD when control is effected by PESS.

Compliance is checked by inspection and operation of the EQUIPMENT.

30.1.4 TREATMENT TIME

a) Controlling timer

EQUIPMENT shall be provided with a CONTROLLING TIMER for each RADIOACTIVE SOURCE or each RADIOACTIVE SOURCE TRAIN

- that can be pre-set to any value of DWELL TIME in an appropriate range,
- that can implement different parts of a prescribed programme of movements and positions of the RADIOACTIVE SOURCES within the TREATMENT TIME if the EQUIPMENT is designed for such implementation,
- that can be pre-set or confirmed only at the TREATMENT CONTROL PANEL,
- that temporarily stops during INTERRUPTION, and
- that automatically TERMINATES IRRADIATION at a treatment position when the CONTROLLING TIMER reaches the pre-set DWELL TIME value.

For the provision of protection in the case of a SINGLE FAULT CONDITION of the CONTROLLING TIMER, see 30.3.2.

Compliance is checked by inspection and operation of the EQUIPMENT.

b) Pre-setting of DWELL TIMES before INITIATION and prevention of changes in the pre-set value

INITIATION shall not be possible until (see 30.1.6)

- at least one DWELL TIME has been pre-set to a value greater than zero, or
- operations have been carried out at the TCP to confirm a set of selections, including DWELL TIMES, when this set of selections is part of a TREATMENT PLAN that has been made by means of a TREATMENT PLANNING SYSTEM that complies with IEC 62083, or
- after operations have been carried out at the TCP to confirm each selection, including DWELL TIMES, when the selection has been made other than at the TCP or other than by means of a TREATMENT PLANNING SYSTEM that complies with IEC 62083.

EQUIPMENT shall be so designed that after INITIATION no change in the pre-set value is possible until the condition of TERMINATION OF IRRADIATION has been reached or induced.

Compliance is checked by inspection and operation of the EQUIPMENT.

30.1.5 Indications by the CONTROLLING TIMER of TREATMENT TIME and DWELL TIME

a) DISPLAY of time

The value(s) at any moment of the SCALE READING(S) of the time(s) being measured by the CONTROLLING TIMER(S) required by 30.1.4a), the pre-set value(s) of DWELL TIME(S) and/or the remaining TREATMENT TIME shall be DISPLAYED on the TREATMENT CONTROL PANEL and also where the operations are made, if this is different from the TREATMENT CONTROL PANEL (see 30.1.7d).

Compliance is checked by inspection and operation of the EQUIPMENT.

b) Counting direction

The DISPLAYED SCALE READING(S) of the CONTROLLING TIMER(S) referred to in 30.1.5a) may either increase from zero or decrease from the pre-set DWELL TIME value.

The DISPLAYED SCALE READING(S) of the remaining TREATMENT TIME shall decrease from the computed value of TREATMENT TIME.

Particularly in the case of long TREATMENT TIMES it is an important safeguard for the USER to see directly how much TREATMENT TIME is still to pass.

In the case of failure of the CONTROLLING TIMER the total duration of IRRADIATION at any treatment position shall be retrievable (see 30.3.2).

Compliance is checked by inspection and operation of the EQUIPMENT.

c) Storage and preservation of information

The SCALE READING(S) referred to in 30.1.5a) shall remain DISPLAYED

- after any TERMINATION OF IRRADIATION until re-set to zero or until the pre-setting operation of 30.1.4b), or until the SUPPLY MAINS is INTERRUPTED (see 30.3.1), and
- after an INTERRUPTION until the subsequent CONTINUATION (see 30.1.7a).

Compliance is checked by inspection and operation of the EQUIPMENT.

30.1.6 Selection and confirmation of CHANNELS, RADIOACTIVE SOURCES, and positions and movements of RADIOACTIVE SOURCES

In EQUIPMENT in which it is possible

- to select from several modes of operation,
- to select from several CHANNELS,
- to select from several individual radioactive sources, or from radioactive sources of different source strengths, or from radioactive sources with different radionuclides, or from several radioactive source trains,

- to select from several positions of the RADIOACTIVE SOURCES,
- to select between a stationary and a moving position for the RADIOACTIVE SOURCES, or
- to select between different programmes of intermittent movement,

the EQUIPMENT shall be so designed and constructed that INITIATION is possible only either

- after operations to make such selections have been carried out at the TREATMENT CONTROL PANEL, or
- after operations have been carried out at the TCP to confirm a set of selections when this set of selections is part of a TREATMENT PLAN that has been made by means of a TREATMENT PLANNING SYSTEM that complies with IEC 62083, or
- after operations have been carried out by the TCP to confirm each selection when the selections has been made other than at the TCP or other than by means of a TREATMENT PLANNING SYSTEM that complies with IEC 62083.

After INITIATION, adjustments to source location shall be permitted only when real-time position information (e.g., fluoroscopy) is available. In this case, a log shall be maintained by the PESS of all source movements. The operations described above shall again be possible only after TERMINATION OF IRRADIATION has been reached or induced.

Compliance is checked by inspection and operation of the EQUIPMENT.

30.1.7 INITIATION, CONTINUATION, INTERRUPTION, and TERMINATION (OF IRRADIATION)

a) EQUIPMENT shall be so designed and constructed that both INITIATION and CONTINUATION are possible only by an operation at the location required in 30.1.7d).

Compliance is checked by inspection and operation of the EQUIPMENT.

b) EQUIPMENT shall be provided with means for INTERRUPTION by causing the automatic return to the STORAGE CONTAINER at any time of all RADIOACTIVE SOURCES not in the STORAGE CONTAINER,

- either by an operation at the location required in 30.1.7d),
- or by the means required in 30.1.8.

The means that causes the automatic return shall not use a PESS to cause or control the return.

Compliance is checked by inspection and by operation of the EQUIPMENT.

c) EQUIPMENT shall be provided with means for TERMINATION (of IRRADIATION) additional to the CONTROLLING TIMER (see 30.1.4)

- that can be activated only after INTERRUPTION, and
- that prevents subsequent movement of the RADIOACTIVE SOURCES from the STORAGE CONTAINER until further pre-setting and selection operations required by 30.1.4b) and 30.1.6 have been carried out, the means being an operation at the location required in 30.1.7d).

Compliance is checked by inspection and by operation of the EQUIPMENT.

d) EQUIPMENT shall be so designed and constructed that the operations referred to in 30.1.7a), 30.1.7b) and 30.1.7c) (except for the means required in 30.1.8) for any one CHANNEL or for any one specified group of CHANNELS may be carried out only at one location that shall be

- either at the TREATMENT CONTROL PANEL,
- or on some single part of the EQUIPMENT,

and that except for equipment designed to be operated in the vicinity of the patient,

- either the TREATMENT CONTROL PANEL, or
- the single part of the EQUIPMENT, whichever is the location of the operations referred to in 30.1.7a), 30.1.7b) and 30.1.7c), can be situated remotely from the STORAGE CONTAINER.

The single part of the EQUIPMENT that is the location for all four operations of INITIATION, CONTINUATION, INTERRUPTION and TERMINATION (of IRRADIATION) for one CHANNEL or specified group of CHANNELS may be different from the single part for another CHANNEL or specified group of CHANNELS when the EQUIPMENT is designed for the simultaneous IRRADIATION of more than one PATIENT.

Compliance is checked by inspection and by operation of the EQUIPMENT.

e) Where the operations referred to in 30.1.7a), 30.1.7b) and 30.1.7c) are not located at the TREATMENT CONTROL PANEL, INITIATION shall be possible only after an operation specifically to attain the READY STATE has been carried out at the TREATMENT CONTROL PANEL.

Compliance is checked by inspection and by operation of the EQUIPMENT.

30.1.8 Distant INTERRUPTION

Except when the device is intended to be operated by an operator in the room, EQUIPMENT shall be provided with connections for devices (e.g., emergency switches) that can be positioned remotely from the location(s) described in 30.1.7d) and that can cause the return to the STORAGE CONTAINER of the RADIOACTIVE SOURCES and prevent their leaving from the STORAGE CONTAINER until an appropriate further operation is carried out. Technical details required for the connection of a suitable device shall be given in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection and by operation of the EQUIPMENT.

30.1.9 Protection against incorrect coupling of the CHANNELS and the SOURCE APPLICATORS

Where the parts of the CHANNELS or SOURCE APPLICATORS are designed to allow uncoupling by the OPERATOR, the EQUIPMENT shall incorporate means for verifying that the parts are correctly coupled and, if this is not the case, either

- prevent the radioactive source(s) from leaving the storage container, or
- ensure that the RADIOACTIVE SOURCE(S) do not move past the point of incorrect coupling and are automatically returned to the STORAGE CONTAINER.

Procedures for INITIATION and CONTINUATION OF IRRADIATION should be addressed in the INSTRUCTIONS FOR USE.

Compliance is checked by inspection and operation of the EQUIPMENT with incorrect coupling.

30.1.10 Limitation of SOURCE STRENGTH of the RADIOACTIVE SOURCE(S)

The total GAMMA SOURCE STRENGTH of the RADIOACTIVE SOURCE(S) used by the EQUIPMENT shall not exceed 100 mGy h^{-1} at 1 m.

The total BETA SOURCE STRENGTH of the RADIOACTIVE SOURCE(S) used by the EQUIPMENT shall not exceed 2 Gy s^{-1} at 2 mm.

The total NEUTRON SOURCE STRENGTH of the RADIOACTIVE SOURCE(S) used by the EQUIPMENT shall not exceed 100 mGy h^{-1} at 1 m.

Compliance is checked by inspection of the technical description (see 6.8.3a) and by inspection of the marking required by 6.1aa).

30.1.11 Recording of the number of RADIOACTIVE SOURCE TRANSIT cycles

A provision shall be made to record the number of RADIOACTIVE SOURCE TRANSIT cycles. This number shall be DISPLAYED or retrievable.

Compliance is checked by inspection.

NOTE If an inactive ("dummy") source is provided that is used to test applicator connections before treatment, similar provisions shall be made for the inactive source.

30.2 Protection against other than NORMAL USE

The following requirements are intended to provide safeguards against unauthorized use and interference.

30.2.1 Rendering the TREATMENT CONTROL PANEL inoperative

EQUIPMENT shall be provided with means whereby the EQUIPMENT can be rendered inoperative. The means could be the removal of the TOOL or key referred to in 30.1.3.

Compliance is checked by inspection.

30.2.2 Protection of RADIOACTIVE SOURCES

EQUIPMENT shall be designed so that access to the RADIOACTIVE SOURCES is impossible without the use of TOOLS.

Compliance is checked by inspection.

30.3 Protection in NORMAL USE while in SINGLE FAULT CONDITION

This subclause specifies the requirements that provide protection against hazards from unwanted or excessive RADIATION while the EQUIPMENT is in any of the following SINGLE FAULT CONDITIONS (each being dealt with in detail in subsequent subclauses):

- failure of the main ENERGY supply (see 30.3.1);
- failure of the CONTROLLING TIMER (see 30.3.2);
- failure of the RADIOACTIVE SOURCES to be in their intended positions (see 30.3.3);
- failure of the SOURCE DRIVE MECHANISM (see 30.3.3c);

- failure of the connections to the RADIOACTIVE SOURCES (see 30.3.4);
- failure of INTERLOCKS (see 30.3.5);
- failure to return a RADIOACTIVE SOURCE to the STORAGE CONTAINER (see 30.3.6).

The indications of single fault conditions are specified in 30.3.9.

30.3.1 Protection during failure of the main ENERGY supply

In the event of a failure of the main ENERGY supply (e.g., SUPPLY MAINS, compressed air, etc.) for the EQUIPMENT:

- TERMINATION OF IRRADIATION shall be automatically induced no later than the end of the TREATMENT TIME and no later than the minimum operating time on the back-up ENERGY supply, whichever comes first.
- The provisions required by subclauses 30.1.2, 30.1.7 (with the exception of INITIATION and CONTINUATION), 30.1.8, 30.1.9 and 30.3 shall remain in force until all RADIOACTIVE SOURCES are returned to the STORAGE CONTAINER.

Instructions regarding maintenance and recharging of batteries or other devices required for compliance with this subclause shall be given in the ACCOMPANYING DOCUMENTS.

Procedures for INITIATION and CONTINUATION OF IRRADIATION shall be addressed in the INSTRUCTIONS FOR USE.

Compliance is checked by inspection and operation of the EQUIPMENT with INTERRUPTION of the SUPPLY MAINS.

30.3.2 Protection during failure of CONTROLLING TIMER

The requirements of this subclause are intended to prevent hazard to the PATIENT and to ensure that the USER can determine the ABSORBED DOSE received by the PATIENT.

a) Limitation of IRRADIATION

The EQUIPMENT shall be so designed and constructed that:

- a failure of the CONTROLLING TIMER (see 30.1.4a) or the electrical supply to a CONTROLLING TIMER controlling the RADIOACTIVE SOURCES in any CHANNEL or group of CHANNELS such that ceasing of IRRADIATION at the current TREATMENT position either is not or will not be induced by the CONTROLLING TIMER at the end of the pre-selected DWELL TIME shall be automatically detected before the patient receives an ABSORBED DOSE of 0,25 Gy at 10 mm for gamma SOURCES, or 2 Gy at 2 mm for beta SOURCES, or a DOSE EQUIVALENT of 0,25 Sv at 10 mm for NEUTRON SOURCES; and
- the RADIOACTIVE SOURCES shall automatically return to the STORAGE CONTAINER as soon as the failure is detected.

The means for satisfying this requirement may be an additional TIMING DEVICE.

Compliance is checked by inducing a suitable failure as specified by the MANUFACTURER and checking the operation of the EQUIPMENT.

b) Check of correct function

INTERLOCKS shall be provided to ensure that the capability of all CONTROLLING TIMERS to induce TERMINATION (of IRRADIATION) has been tested and proved satisfactory prior to INITIATION.

Compliance is checked by inspection and by operation of the EQUIPMENT.

30.3.3 Protection during failure of the positional accuracy and movement of the RADIOACTIVE SOURCES and of the SOURCE DRIVE MECHANISM

a) Protection during failure of the positional accuracy of the RADIOACTIVE SOURCES during treatment

EQUIPMENT shall be provided with means whereby if any RADIOACTIVE SOURCE at any time during treatment fails to be in its intended position (within the tolerances specified by the MANUFACTURER),

- such failure shall be detected, and
- as soon as failure is detected, the RADIOACTIVE SOURCE(S) shall be automatically returned to the STORAGE CONTAINER.

Compliance is checked by inspection and operation of the EQUIPMENT in such a way as to cause an appropriate failure as specified by the MANUFACTURER.

b) Protection during failure of movement of a RADIOACTIVE SOURCE during TRANSIT

EQUIPMENT shall be provided with means whereby if any RADIOACTIVE SOURCE at any time during TRANSIT fails to move to its intended position (within the tolerances specified by the MANUFACTURER),

- such failure shall be detected, and
- as soon as the failure has been detected, the RADIOACTIVE SOURCE(S) shall be automatically returned to the STORAGE CONTAINER.

Compliance is checked by inspection and operation of the EQUIPMENT in such a way as to cause an appropriate failure as specified by the MANUFACTURER.

c) Protection during failure of the SOURCE DRIVE MECHANISM

To provide protection against failure of the electrical supply to, the control of, or the function of electrical components of the SOURCE DRIVE MECHANISM, EQUIPMENT shall be provided with alternative means:

- independent of the normal electrical part of the SOURCE DRIVE MECHANISMS, and
- capable of being operated to return the RADIOACTIVE SOURCE(s) to the STORAGE CONTAINER.

Compliance is checked by inducing an appropriate failure as specified by the MANUFACTURER and operating the equipment or by inspection.

30.3.4 Protection against failure of the connections (if any) to the RADIOACTIVE SOURCES

Where the EQUIPMENT has demountable mechanical connections between the RADIOACTIVE SOURCES and the SOURCE DRIVE MECHANISM, means shall be provided to test automatically the mechanical connection after this connection is made before treatment is initiated.

The force that the SOURCE DRIVE MECHANISM can automatically apply to the SEALED RADIOACTIVE SOURCE(S) shall be limited to one fourth of the force that the SEALED RADIOACTIVE SOURCE(S) or the mechanical connection to the SEALED RADIOACTIVE SOURCE(S) can withstand.

Compliance is checked by inspection of the EQUIPMENT and of the MANUFACTURER'S relevant information (i.e. test results, calculations, specifications of materials used and of processing specifications for these materials.)

30.3.5 Protection against failure of INTERLOCKS

Facilities shall be provided so that the correct function of all radiation safety INTERLOCKS can be checked.

Compliance is checked by inspection.

30.3.6 Detection of failure to return a RADIOACTIVE SOURCE to the STORAGE CONTAINER

EQUIPMENT shall be provided with means, based on the detection of the RADIATION of the RADIOACTIVE SOURCE(S), to detect a failure of a RADIOACTIVE SOURCE to return to the STORAGE CONTAINER.

Compliance is checked by inspection and operation of the EQUIPMENT in such a way as to cause an appropriate failure as specified by the MANUFACTURER.

30.3.7 Availability of information regarding the CONTINUATION of IRRADIATION

In the event of any failure described in 30.3.1, 30.3.2a), 30.3.3a), 30.3.3b) and 30.1.9, information necessary to continue IRRADIATION according to the preset parameters shall be retrievable for a period of at least 10 h from the time of failure or until a permanent record has been made (see also 50.2.3)

Compliance is checked in the same way as for 30.3.1, 30.3.2a), 30.3.3a), 30.3.3b) and 30.1.9.

The ACCOMPANYING DOCUMENTS shall contain an explanation of the procedures(s) to retrieve this information and to restore this information to continue the TREATMENT

Compliance is checked by examination of the ACCOMPANYING DOCUMENTS.

30.3.8 Correction prior to further IRRADIATION

Subsequent to any failures described in 30.3.2 a), 30.3.3 a) and 30.3.3 b), neither INITIATION nor CONTINUATION shall be possible by NORMAL USE. The ACCOMPANYING DOCUMENTS shall contain:

- specific instructions on corrective actions for each of the failures described in 30.3.2 a), 30.3.3 a) and 30.3.3 b)
- an explanation of the special procedures(s) that should be carried out.

Compliance is checked in the same way as for 30.3.2 a), 30.3.3 a) and 30.3.3 b).

30.3.9 Indication of SINGLE FAULT CONDITIONS

a) Indication(s) of failure

EQUIPMENT shall be provided with indicator lights complying with 6.7 or other means of indication that are activated when any of the following failures has occurred:

- failure of a CONTROLLING TIMER (see 30.3.2);
- failure of movement of a RADIOACTIVE SOURCE (see 30.3.3b);

- failure of a SOURCE DRIVE MECHANISM (see 30.3.3c);
- failure of a coupling of the CHANNEL and the SOURCE APPLICATOR (see 30.1.9);
- failure of the connection to a RADIOACTIVE SOURCE (see 30.3.4);
- failure of an INTERLOCK when EQUIPMENT has the means to detect failure of the radiation safety INTERLOCK (see 30.3.5);
- failure to return a RADIOACTIVE SOURCE to the STORAGE CONTAINER (see 30.3.6).

Compliance is checked by inspection and by operation with a fault as specified by the MANUFACTURER.

b) Indication of failure of movement of a RADIOACTIVE SOURCE

Following an INITIATION of movement, if any RADIOACTIVE SOURCE does not arrive at its intended position, an audible alarm and a visible indication at the location required by 30.1.7d) shall be initiated immediately and sustained until switched off.

Compliance is checked by inspection and by operation with a fault as specified by the MANUFACTURER.

c) Indication that radiation safety INTERLOCKS have operated because of SINGLE FAULT CONDITIONS

EQUIPMENT shall be provided with means to indicate visually when normal movement of the RADIOACTIVE SOURCES has been prevented by any of the conditions referred to in subclauses 30.3.2a), 30.3.2b), 30.3.3a), 30.3.3b) and 30.3.4.

Compliance is checked by inspection.

d) Indication that initiation is prevented or irradiation is terminated because of single fault conditions.

EQUIPMENT shall be provided with means to indicate visually when movement of the RADIOACTIVE SOURCES has been prevented by any of the conditions referred to in 30.3.9

Compliance is checked by inspection.

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard do not apply.

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

The clauses and subclauses of this section of the General Standard apply.

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

The clauses and subclauses of this section of the General Standard apply except as follows:

50 Accuracy of operating data

This clause of the General Standard applies except as follows:

50.1 Marking of controls and instruments

Replacement:

50.1 Indications

50.1.1 Information on gamma, beta, and NEUTRON IRRADIATION

Adequate information shall be provided in the ACCOMPANYING DOCUMENTS about selectable modes of operation and choices and configurations of RADIOACTIVE SOURCES to enable the USER to select appropriate conditions for the IRRADIATION and to obtain data necessary for the estimation of the ABSORBED DOSE RATE.

Compliance is checked by inspection.

50.1.2 Scales and units

Except for the display of time, each scaled DISPLAY of the value of a parameter relating to output shall have only one scale in a unit of only one kind and/or its decimal subdivisions. For the DISPLAY of time values in hours or minutes, decimal subdivisions shall not be used. All DISPLAYS of parameter values shall identify the units of the parameter.

Compliance is checked by inspection.

50.1.3 Indication of selection of CHANNELS, RADIOACTIVE SOURCES, and the positions and movements of RADIOACTIVE SOURCES

Where the RADIOACTIVE SOURCE(S) may be used in different configurations and/or at different stationary and/or moving positions in any CHANNEL, an indication of all selected configurations, positions and movements of RADIOACTIVE SOURCES in each CHANNEL shall be given and maintained until re-selected.

Compliance is checked by inspection and by operation of the EQUIPMENT.

50.1.4 Information required for limiting irradiation during transit of the RADIOACTIVE SOURCES

There are three objectives of limiting IRRADIATION during the TRANSIT of the RADIOACTIVE SOURCES. One is to limit the IRRADIATION that is given under undetermined conditions to the PATIENT'S TARGET VOLUME. The second is to limit the ABSORBED DOSE to normal tissues during normal TRANSIT of the RADIOACTIVE SOURCE. The third is to limit the EQUIVALENT DOSE received by the OPERATOR(S) of the EQUIPMENT.

Such TRANSIT doses are partly determined by the time taken by the TRANSIT movements, but they are also determined by the SOURCE STRENGTH of the RADIOACTIVE SOURCES selected by the USER and by the number of INTERRUPTIONS during TREATMENT. It is therefore necessary for the USER to have information from which the TRANSIT doses may be estimated and to take appropriate account of them.

The information on TRANSIT dose given in the ACCOMPANYING DOCUMENTS shall relate to measurements or calculations for two conditions and for each CHANNEL (see 6.8.2ee):

- the AIR KERMA at a position 10 mm from the axial centre of the SOURCE APPLICATOR, for RADIOACTIVE SOURCES emitting gamma RADIATION,
- the ABSORBED DOSE to water at a position 2 mm from the axial centre of the SOURCE APPLICATOR for RADIOACTIVE SOURCES emitting beta RADIATION,
- the ABSORBED DOSE to water at a position 10 mm from the axial centre of the SOURCE APPLICATOR for RADIOACTIVE SOURCES emitting NEUTRON RADIATION,
- the AIR KERMA at a position 1 m from the axial centre of the channel for RADIOACTIVE SOURCES emitting gamma RADIATION, and
- the ABSORBED DOSE to water in free space at a position 1 m from the axial centre of the CHANNEL for RADIOACTIVE SOURCES emitting beta RADIATION and NEUTRON RADIATION.

For each condition AIR KERMA or ABSORBED DOSE shall be given for one specified RADIOACTIVE SOURCE and shall be at the positions that are least favourable with regard to this requirement.

If measurements are made either to provide the information or to test compliance:

- for measurements at 10 mm the AIR KERMA shall be averaged over an area up to but not exceeding 1 cm^2;
- for measurements at 2 mm the ABSORBED DOSE to water shall be averaged over an area up to but not exceeding 1 mm^2;
- for measurements at 1 m the AIR KERMA or ABSORBED DOSE to water shall be averaged over an area up to but not exceeding 100 cm^2.

50.2 Agreement between indicated value and effective values

50.2.1 Position of RADIOACTIVE SOURCES within SOURCE APPLICATORS

The indication (see 30.1.2c) that the position of any RADIOACTIVE SOURCE (or RADIOACTIVE SOURCE TRAIN) within any SOURCE APPLICATOR supplied with the EQUIPMENT is as selected shall be given only when the position deviates by not more than 2 mm in any direction relative to the specified position.

A description of the conditions of the SOURCE APPLICATOR and CHANNEL under which the above agreement does not hold shall be given in the ACCOMPANYING DOCUMENTS (see 6.8.2ff).

Compliance is checked by inspection and by means devised and explained by the MANUFACTURER.

50.2.2 CONTROLLING TIMERS

The error of the value of the DWELL TIME shall not exceed 1 % or 100 ms whichever is greater.

Compliance is checked by:

- *selecting 5 pre-set times (not smaller than 1 % of the maximum pre-settable value) to cover the range possible with the device;*

- *carrying out at each of the pre-set times 10 measurements of the actual duration in the intended position and/or carrying out the intended movements (for example, by taking electrical signals for the arrival of the RADIOACTIVE SOURCE at the SOURCE APPLICATOR and its departure obtained as specified by the MANUFACTURER);*

Each of the measurements shall comply with the requirement.

50.2.3 Record of IRRADIATION

At TERMINATION OF IRRADIATION the EQUIPMENT shall have available the following data:

- unique PATIENT identifier, preferably the name and date of birth of the PATIENT;
- date and time of INITIATION;
- time of termination of irradiation;
- time of any INTERRUPTION;
- time and date of any CONTINUATION;
- SOURCE STRENGTH, date and time of last calibration of each RADIOACTIVE SOURCE;
- CHANNEL, RADIOACTIVE SOURCE position and DWELL TIME of each treatment position.

These data shall be retrievable for a period of at least 10 h from the time of any failure mentioned in 30.3.7

Compliance is checked by inspection.

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply, except as follows:

52 Abnormal operation and fault conditions

52.1 *Replacement*

a) EQUIPMENT shall be so designed and manufactured that, even in SFC, no SAFETY HAZARD exists (see 3.1 and Clause 13).

NOTE It is assumed that EQUIPMENT is operated according to the conditions of NORMAL USE, unless specified otherwise in the following tests.

Compliance is fulfilled if the introduction of any of the SFCs described in 52.5, one at a time, does not lead directly to any of the SAFETY HAZARDS described in 52.4.

b) The safety of EQUIPMENT incorporating PROGRAMMABLE ELECTRONIC SUBSYSTEMS shall be assessed against the requirements of IEC Collateral Standard 60601-1-4 (see Appendix L).

All relevant information regarding RESIDUAL RISK shall be included in the INSTRUCTIONS FOR USE.

Exception: IEC 60601-1-4 shall not be applied to projects/products when it can be shown that development has progressed beyond the stage where its detailed requirements could be applied; it has to be applied during project/product development and continued throughout the DEVELOPMENT LIFE-CYCLE.

Although it will not be possible to apply IEC 60601-1-4 fully in retrospect to existing products and to those that have progressed beyond the stage identified above, examination of available design and process control data may provide substantial verification, see also 52.211.1 of IEC 60601-1-4.

Compliance is checked by inspection of the INSTRUCTIONS FOR USE and IEC 60601-1-4 RISK MANAGEMENT FILE.

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

The clauses and subclauses of this section of the General Standard apply.

Appendix L
(normative)

References – Publications mentioned in this standard

This appendix of the General Standard applies, except as follows:

Addition:

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Addition:

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61217:1996, *Radiotherapy equipment —Coordinates, movements and scales* [1]
Amendment 1 (2000)

IEC 62083:2000, *Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems*

Replacement:

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:2001, *Medical electrical equipment – Part 1-2: General requirements for safety –Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems* [2]
Amendment 1 (1999)

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[1] There exists a consolidated edition 1.1 (2000) that includes IEC 61217 (1996) and its Amendment 1 (2000).

[2] There exists a consolidated edition 1.1 (2000) that includes IEC 60601-1-4 (1996) and its Amendment 1 (1999).

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IEC 60601-1-3:1994 *Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*

ICRP Publication 33:1982 *Protection Against Ionizing Radiation from External Sources Used in Medicine*

ICRP Publication 60:1991 *1990 Recommendations of the International Commission on Radiological Protection*

ICRU Report 35:1984 *Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV.*

ICRU Report 38:1985, *Dose and Volume Specification for Reporting Intracavitary Therapy in Gynecology*

ICRU Report 39:1985, *Determination of Dose Equivalents Resulting from External Radiation Sources*

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ICRU Report 58:1997,. *Dose and Volume Specification for Reporting Interstitial Therapy*

AAPM Report 61:1998, *High Dose-Rate Brachytherapy Treatment Delivery* (Reprinted from Medical Physics, Vol. 25, Issue 4) (1998) Radiation Therapy Committee Task Group No. 59; 29 pp.

International Atomic Energy Agency Safety Series No. 115:1996, *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources*

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International Standard	*Title*
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IEC 60601-1-4 : 2000	Medical electrical equipment — Part 1-4: General requirements for safety — Collateral standard: Programmable electrical medical systems

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